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| APPLICATION NO.                  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------------|-------------|----------------------|---------------------|------------------|
| 10/002,424                       | 10/31/2001  | Roman Turovkiy       | 267/177             | 3071             |
| 30452                            | 7590        | 06/07/2004           | EXAMINER            |                  |
| EDWARDS LIFESCIENCES CORPORATION |             |                      | WOO, JULIAN W       |                  |
| ONE EDWARDS WAY                  |             |                      | ART UNIT            |                  |
| IRVINE, CA 92614                 |             |                      | PAPER NUMBER        |                  |
|                                  |             |                      | 3731                |                  |

DATE MAILED: 06/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/002,424 | <b>Applicant(s)</b><br>TUROVKIY ET AL. |  |
|                              | <b>Examiner</b><br>Julian W. Woo     | <b>Art Unit</b><br>3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 is/are pending in the application.  
     4a) Of the above claim(s) 5-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/31/01</u> . | 6) <input type="checkbox"/> Other: _____  |

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### DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-4, drawn to an obturator, classified in class 606, subclass 170.
  - II. Claims 5-12, drawn to a method for introducing a medical device during cardiovascular surgery, classified in class 128, subclass 898.
2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case, the process as claimed can be practice with another materially different apparatus, such as a catheter or a port.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

3. In a voice mail from Diane Wong, Reg. No. 54, 550, on May 28, 2004, a provisional election was made without traverse to prosecute invention I, claims 1-4. Affirmation of this election must be made by applicant in replying to this Office action. Claims 5-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one

or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Objections***

4. Claim 1 is objected to because of an informality, which can be corrected as follows: In line 1, after "An," insert –obturator–. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 1, "the actuating member" lacks antecedent basis.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Gordin (3,885,308). With respect to claims 1 and 2, Gordin discloses, in figures 1-5, a device usable as an obturator, where the device comprises an elongate tubular member

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(11) with a slot (28) at its distal end, a blade (23); and an actuating mechanism having a force biasing element (26) or spring, a rotary element (36), a retaining element (19), and a release (16), where a force applied to the release slideably rotates the rotary element to engage the release, causing the blade to advance beyond the slot (see fig. 2) and, when the force is applied again to the release, slideably rotates the rotary element to disengage from the release, causing the blade to retract into the slot (see figs. 3 and 5). With respect to claim 4, Gordin discloses, in figure 1, a pocket clip or introducer with an elongate tubular member, proximal and distal ends, and a lumen adapted to receive the obturator.

***Allowable Subject Matter***

8. Claim 3 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses an obturator with, inter alia, an actuating mechanism having a finger-actuated button that, when depressed, rotates the actuating mechanism to alternately engage and disengage a retaining element of the mechanism.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sleister et al. (5,522,831) teach an obturator with an elongate tubular member, a blade, and an actuating mechanism.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (703) 308-0421. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

General inquiries relating to the status of this application should be directed to the Group receptionist at (703) 308-0858. The official FAX number is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink that reads "Julian W. Woo". The signature is written in a cursive, flowing style.

Julian W. Woo  
Primary Examiner

June 2, 2004